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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,808	ESSER ET AL.	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on 15 September 2008.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Claims 1-20 are pending in the application.

Claims 1-9 and 11-13 are presented for examination on the merits as they are drawn to the species "APT3820" [bis-myristoyl-KSSKSPSKKDDKKPGDC] and bis-myristoyl-GSSKSPSKKKKKKPGDC. Claims 10, 14-20 are withdrawn as not drawn to the elected group/species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude

that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the

disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a modified therapeutic agent, said modified agent comprising three or more membrane binding elements with low membrane affinity covalently associated with the polypeptide which elements are capable or interacting, independently and with thermodynamic additivity, with components of cellular or artificial membranes exposed to extracellular fluids, wherein at least two membrane binding elements are lipophilic elements. In regards to the "membrane binding elements with a low membrane affinity" term, this is a very broad generic statement drawn the element has a measurable but relatively low affinity for membranes, that is a dissociation constant greater than 1 uM, preferably 1 um - 1mM. The elements preferably have a size < 5 kDa, and may consist of basic amino acid elements and two lipophilic elements (see disclosure, page 2, 5th paragraph) there exists a plethora of such compounds, which are not adequately described and/or represented in the examples. By the same token, the term "lipophilic element" appears to be correlated with aliphatic acyl groups, however the term is much broader. The claims are drawn to modified therapeutic agents, wherein the therapeutic agent may be any therapeutic agent, including anticancer and antibacterial agents and soluble proteins which are complement inhibitors, therefore a mere statement that such

compounds would be desirable for conjugation with membrane biding elements does not sufficiently provide ample written description pages describing the full breadth of the therapeutic agents and specifically of the covalent conjugates with lipophilic elements and other membrane binding elements with biological activity as instantly claimed. The specification does provide examples of what qualify as compounds of the claimed invention (see, e.g, page 6, Table 1, page 7; pages 12-28), however, these are limited to a few examples such as synthesis and purification of a few bis-myristolylated peptide conjugates drawn to small peptides, a conjugate with CD59, a few anti-hemolytic and anti-complement activity assays and further conjugation to SCR1-3. Please note that the broad claim describes a very broad desirable modified agent however, there is no adequate representation of the breadth of the instantly claimed modified agents with biological activity as instantly claimed. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of therapeutic agent with two or more lipophilic elements. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples

of conjugates with e.g., other lipophilic elements such as oleic acids, heterocyclic lipophilic components, phospholipid conjugates, and so forth. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Applicant's Arguments

The examiner asserts that the term "membrane binding elements with a low membrane affinity" is a broad generic statement. The examiner also asserts that the specification does not provide sufficient variety of species to reflect the variance in the genus. The examiner agree that the elements having a size of <5kDa having basic amino acid elements and two lipophilic elements are disclosed in the specification (see specification, for example, page 2, 5th paragraph). The examiner also agrees that the specification does provide examples of what qualify as compounds of the claimed invention (see for example, page 6, Table 1, page 7; pages 12-28).

However, the examiner asserts that these are not adequately described and/or represented in the examples and are limited to a few examples such as synthesis and purification of a few bis-myrostolylated peptide conjugates drawn to small peptides, a conjugate with CD59, a few anti-hemolytic and anti-complement activity assays and further conjugation to SCR1-3.

Applicants respectfully disagree with the examiner and invite the examiner to consider MPEP 2164.02 (Rev 6, September 2007) with regards to enablement, at 2100-196.

As clarified above and as agreed by the examiner, the specification provides working examples and discloses a number of species. Therefore, the invention is disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In view of the above clarifications, applicants submit that the written description requirement is met and the applicants were in possession of the claimed inventions at the time the application was filed. Accordingly, withdrawal of the written description/enablement rejection is solicited.

Response to Arguments

Applicants' arguments have been carefully considered by examiner but not deemed persuasive for the following reasons:

First of all, the examiner emphasizes that the rejection made was a written description rejection, not an enablement rejection. Applicant has not shown possession of the entire genus of modified therapeutic agents comprising three or more membrane binding elements with low membrane affinity covalently associated with the agent which elements are capable of interacting independently and with thermodynamic additivity, with components of cellular or artificial membranes exposed to extracellular fluids wherein at least two membrane binding elements are lipophilic elements as instantly claimed. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification and in claim 11, however, the broad claims are still drawn to conjugates with any and all therapeutic agents and which still retain their therapeutic ability after conjugation with any and all membrane binding elements with low membrane affinity covalently associated with the agent which elements are capable of interacting independently and with thermodynamic additivity. One skilled in the art would not be able to identify without further testing further membrane binding elements with low membrane affinity which are capable of interacting independently and with thermodynamic additivity and conjugating them with any therapeutic agent available wherein the therapeutic agent's activity is retained / enhanced. Based on the lack of guidance and predictability in the art, those of ordinary skill in the art would not conclude that the applicant was in possession of the claimed genus of modified therapeutic agents based on the disclosure of the single series of synthesis and purification of a few bis-myrostolylated peptide conjugates drawn to small peptides, a conjugate with CD59, a few anti-hemolytic and anti-complement activity assays and further conjugation to SCR1-3. Therefore the specification fails to satisfy the written description requirements of 35 USC 112, first paragraph, with respect to claims 1 and dependent claims thereof (except for claims 11-12). See, e.g., Written description guidelines, e.g., example 10 at http://www.uspto.gov/web/menu/written.pdf .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-9, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (US 6,713,606).

Smith et al. teach a modified therapeutic agent, said modified agent comprising three or more membrane binding elements with low membrane affinity covalently associated with the polypeptide which elements are capable or interacting, independently and with thermodynamic additivity, which components of cellular or artificial membranes exposed to extracellular fluids (e.g., column 2, lines 45-51) wherein at least two membrane binding elements are lipophilic elements (e.g., claim 8(a) of Smith et al. which teaches 'at least one lipophilic binding element comprising aliphatic acyl groups. See also column 4). The limitation of claim 6: --wherein the agent is a soluble protein— and the limitation of claim 7: --wherein the soluble protein is a complement inhibitor—are taught, e.g., in claim 1(1) of Smith. The limitations of claim 8: --wherein the agent is an anticancer agent-- and of claim 9: --wherein the agent is an antibacterial agent-- are inherent to the composition of Smith et al. since it anticipates all the structural and functional limitations of the instant invention. The limitations of claims 12: -a pharmaceutical composition comprising [...] a pharmaceutically acceptable excipient-- and the limitation of claim 13: --wherein the agent is for use as a medicament—are taught in claim 8 of Smith et al.

Therefore, the reference is deemed to anticipate the instant claims above.

Applicant's arguments

Applicants respectfully disagree with the examiner and point out that the examiner has not shown that the cited references disclose each and every element of the claimed method. MPEP 2131 at 2100-67 (Rev. 6, September 2008).

Applicants also refer to the specification (see pages 3-4, for example), which clarifies the surprising discovery that the claimed modified therapeutic agent comprising three or more membrane binding elements has unexpected advantages over the previously known agents. The examiner has not cited to any reference disclosing a "modified therapeutic agent comprising three or more membrane binding elements."

Response to arguments

Applicant's arguments have been carefully considered, but not deemed persuasive for the reasons of record and because as previously pointed out the limitation "comprising three or more membrane binding elements" is taught, e.g., in column 2, lines 45-67. With regards to anticipation of ranges, see, e.g., MPEP 2131.03, which teaches

> When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See, e.g., *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure of a range is no more a disclosure of the end

> points of the range than it is each of the intermediate points." *Id.* at 1000, 78 USPQ2d at 1424. Any evidence of unexpected results within the narrow range may also render the claims unobvious. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See MPEP § 2131.02. A 35 U.S.C. 102/ 103 combination rejection is permitted if it is unclear if the reference teaches the range with "sufficient specificity." The examiner must, in this case, provide reasons for anticipation as well as a *>reasoned< statement regarding obviousness. *Ex parte Lee*, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993) (expanded Board). For a discussion of the obviousness of ranges see MPEP § 2144.05.

In the instant case: 2 or more membrane binding elements with the instantly claimed characteristics and functions covalently bound to a polypeptide as cited above overlaps with the claimed invention encompassing 3 or more membrane binding elements covalently bound to a polypeptide identical to the one taught by Smith et al.

Therefore the 102 rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mossakowska et al. (US 2003/0064431).

Mossakowska et al. teach a modified therapeutic agent (GSSKSPSKKKKKKPGDC, Examples 5, 7, 9) said modified agent comprising a membrane binding element (myristoyl- [0047], [0060], [0079]) with low membrane affinity ([0049]) covalently associated with the agent which elements are capable of

interacting independently and with thermodynamic additivity ([0047]), with components of cellular or artificial membranes exposed to extracellular fluids. Mossakowska teach also preferred embodiments in [0072] the following structure: [P]-{L-[W]}$_n$-X, wherein P is soluble peptide (such as GSSKSPSKKKKKKPGDC), L a flexible linker group, W is a peptidic membrane binding element, n is 1 or more, X is a peptidic or non-peptidic membrane binding entity which may be covalently linked to any W. Please note that W can be the fatty acid derivative myristoyl ([0147], [0060], [0079]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Mossakowska et al. by making the preferred composition [P]-{L-[W]}$_n$-X with a soluble peptide such as the one exemplified in Examples 5, 7 and 9 with the preferred W = myristoyl, with X greater than 2 as also taught by Mossakowska et al. The skilled artisan would have been motivated to do so because such compositions are preferred embodiments and P is taught to be GSSKSPSKKKKKKPGDC (Examples 5, 7, 9). There would have been a reasonable expectation of success, given that such compositions were encompassed by the invention of Mossakowska et al. The limitations of claims 8-9: "anticancer agent" and "antibacterial agent" necessarily read upon the compound of Mossakowska et al. as it contains the structural and functional limitations instantly claimed. The limitations of claim 12: "pharmaceutical composition' and claim 13: "wherein the agent is for use as a medicament" are taught, e.g., in claims 25-26. The adjustment of particular conventional working conditions (e.g., selecting 2 or more myristoyl lipophilic elements within such method) is deemed merely a matter of judicious selection and routine optimization that

is well within the purview of the skilled artisan. As such, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g., adjusting the lipophilic elements), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.". *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2145.05). One would have been motivated to determine all optimum and operable conditions in order to achieve the highest yield of the highest purity product in the most efficient manner. One would have had a reasonable expectation for success because such modifications are routinely determined and optimized in the art through routine experimentation.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments

Applicant states that US/0064431 was published on April 3, 2003, while the instant application claims priority to GB0220936, filed September 5, 2002. The GB application fully supports the claims. See, for example, pages 3-7, including SEQ ID

NOs: 2 and 6-10. Therefore Mossakowska et al. is not prior art against the claimed invention.

Additionally Applicant cites MPEP 2144,09 with regard to unexpected advantageous or superior properties.

Response to Applicants

Applicants have not provide any evidence of unexpected results with regards to the superior properties of the claimed modified therapeutic, indeed, the products overlap structurally, therefore any unexpected properties would be shared by the Mossakowska et al. invention and the instant invention. Additionally, please note that the Mossakowska el al. application is also prior art under 102(e), therefore, the 103 rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-10, 13-14 of U.S. Patent No. 6,713,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a modified therapeutic agent comprising three or more membrane binding elements with low membrane affinity (e.g., claim 1 in US '606) covalently associated with the agent which elements are capable of interacting independently and with thermodynamic additivity with components of cellular membranes exposed to extracellular fluids wherein at least two membrane binding elements are lipophilic elements (see claim 8 (2a) in US '606). Further, the instantly claimed composition encompasses and/or is encompassed by the claimed composition of US '606.

Applicant's arguments

Applicants will submit a terminal disclaimer upon receipt of the examiner intent of an allowance.

Response to Arguments

The ODP rejection is therefore maintained.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Marcela M Cordero Garcia/
Examiner, Art Unit 1654

MMCG 12/08